Addendum to Data Evaluation Record

MRID: 47560121

PC Codes: 288008 288009 288010

OCSPP Guideline: 850.2300 Avian Reproduction

Date: May 6, 2014

DER Study Title: Temple, D.L., *et al.* 2008. DPX-MAT28 Technical: A Reproduction Study with the Northern Bobwhite. Unpublished study performed by Wildlife International Ltd., Easton, MD. Laboratory Project No. 112-602. Study sponsored by E.I. du Pont de Nemours and Company, Wilmington, DE. Study initiated September 10, 2007 and submitted June 24, 2008.

Changes Made: Change in status, from invalid to acceptable.

Rationale: The study was originally classified invalid (A. Ullagaddi, 10/05/2009, DP Barcode 358148), because the cage size was considerably smaller than preferred by the draft OPPTS 850.2300 guideline, the initial age of the test birds was younger than recommended, pre-test health (including mortality) of the adult birds was not reported, and frozen storage stability data were not provided. Of these deviations, cage size was the original reviewer's preeminent concern. However, cage size recommendations are no longer as prescriptive in the final OCSPP 850.2300 guideline published in June 2012. OCSPP guideline 850.2300 states: "The Agency recognizes that minimum cage size recommendations are evolving over time. The use of a certain cage size, as with any husbandry parameter, should result in control birds with no overt signs of stress (e.g., reproductive results are within test validity elements reported in this guideline). Northern bobwhite and mallards should be housed in breeding pens or cages of adequate size conforming to good husbandry practices." All established validity criteria for the controls were met. While cage size may have been directly or indirectly responsible for the mortalities and injuries recorded in this study, the frequency and severity of recorded effects do not reduce confidence that the test remained sufficiently robust to detect treatment-related effects to study endpoints.

TEXT SEARCHABLE DOCUMENT - 2010

Data Evaluation Report on the Reproductive Effects of DPX-MAT28 Technical (Aminocyclopyrachlor) on Northern Bobwhite Quail (Colinus virginianus)

PMRA Submission Number {......}

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Data Requirement:	PMRA	Data Code	{}		
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	OECD	Data Point	{}		
	EPA M	RID	47560121		
	EPA G	uideline	850.2300		
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	•	* .			
	X-MAT28 Technical		Purity: 92.29	⁄o	
Common name An	ninocyclopyrachlor				
Ch	emical name:				
I	UPAC: 6-amino-5-chl	oro-2-cycloprop	ylpyrimidine-4-carbo	xylic acid	
. (CAS: 6-amino-5-chlore	o-2-cyclopropyl-	4-pyrimidinecarboxyl	ic acid	
CA	S No.: 858956-08-8				
Syn	nonyms: None reporte	d			
			/	Christia E. Padova	
Primary Reviewer:			Signature: C	hristie C. I adova-	
Staff Scientist, Dyna	amac Corporation		Date: 07/14/0)9	
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EPA PC Code	None assigned	[

Date Evaluation Completed: 10/05/09

<u>CITATION</u>: Temple, D.L., *et al.* 2008. DPX-MAT28 Technical: A Reproduction Study with the Northern Bobwhite. Unpublished study performed by Wildlife International Ltd., Easton, MD. Laboratory Project No. 112-602. Study sponsored by E.I. du Pont de Nemours and Company, Wilmington, DE. Study initiated September 10, 2007 and submitted June 24, 2008.

DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the reproductive effects of a pesticide on avian species. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

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EXECUTIVE SUMMARY

The one-generation reproductive toxicity of DPX-MAT28 Technical (aminocyclopyrachlor) to 16 pairs per level of 20-week old Northern bobwhite quail (*Colinus virginianus*) was assessed over *ca.* 22 weeks. DPX-MAT28 was administered to the birds in the diet at nominal concentrations of 0 (control), 160, 400, or 1000 mg ai/kg dw diet (adjusted for purity). Mean-measured concentrations were <LOD (control), 159, 382, and 994 mg ai/kg diet, respectively.

The scientific soundness of this study is questionable study due to the significantly smaller cage size used in the study than recommended in the guideline. Because seven incidental mortalities, which may be attributable to small cage size, occurred during the study, cage size may have affected the reproductive endpoints measured in this study in all treatment levels, including the controls. This study is classified as invalid. It does not satisfy the guideline requirement for a Northern bobwhite quail (*Colinus virginianus*) reproductive toxicity study.

Results Synopsis

Test Organism Size/Age (mean Weight): 20-weeks old; 179 to 234 g (combined sexes)

NOAEC: N/A LOAEC: N/A

Endpoint(s) Affected: N/A

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: U.S. EPA Pesticide Assessment Guidelines, §71-4 (1982)

OECD Guideline No. 206 (1984) ASTM Standard E1062-86 (1986)

U.S. EPA OPPTS Guideline No. 850.2300 (1996)

Deviations from OPPTS Guideline No. 850.2300 included:

- 1. The initial age of the test birds (20 weeks) was younger than recommended (at least 30 weeks old).
- 2. Pre-test health (including mortality) of the adult birds was not reported.
- 3. Cage size was significantly smaller than recommended. OPPTS recommends at least 5,000 cm² per bird. In this study, the floor space was only 638 cm² per bird.
- 4. Although acceptable ambient 7-day feeder trough stability was demonstrated, frozen storage stability data were not provided. Premix batches were prepared every 2 to 4 weeks, and stored frozen in plastic bags until needed (see Reviewer's Comments section).

These deviations, specifically cage size, may affect the scientific soundness of this study.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality

statements were provided. This study was conducted in compliance with the GLP Standards as published in the 40 CFR, Part 160 with the following exception: routine analysis of food and water for potential contaminants.

A. MATERIALS:

1. Test Material DPX-MAT28 Technical (aminocyclopyrachlor)

Description: Solid

Lot No./Batch No.: 009

Purity: 92.2%

Stability of compound

under test conditions: The 7-day stability of DPX-MAT28 Technical (aminocyclopyrachlor) was

verified at all treatment levels under actual-use conditions during Week 3.

Recoveries were 97 to 112% of initial measured concentrations.

(OECD recommends water solubility, stability in water and light, pKa, Pow, and vapor pressure of test compound)

Storage conditions of

test chemicals: Ambient conditions

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Physicochemical properties of Aminocyclopyrachlor.

Parameter	Values	Comments
Water solubility at 20°C	Not reported	
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

2. Test organism:

Table 1: Test organism.

Parameter	Details	Remarks
1 वा वागटाचा		Criteria
Species (common and scientific names):	Northern bobwhite quail (Colinus virginianus)	Birds were from the same hatch, and were phenotypically indistinguishable from wild birds.
		Recommended species include a wild waterfowl species, preferably the mallard (Anas platyrhynchos) or an upland game species, preferably the northern bobwhite (Colinus virginianus)
Age at Study Initiation:	20 weeks old	Birds were younger than recommended (≥30 weeks). It was stated that birds were approaching their first breeding season.
		Birds approaching their first breeding season should be used.
Body Weight: (mean and range)	Males: Overall range (n=64) of 179 to 233 g, with group means of 197 to 201 g.	Body weights were recorded at weeks 0, 2, 4, 6, 8, 10, and 22 (adult termination).
	Females: Overall range (n=64) of 180 to 234 g, with group means of 197 to 202 g.	Body weights should be recorded at test initiation and at biweekly intervals up to week eight or up to the onset of egg laying and at termination.

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Parameter	Details	Remarks
		Criteria
Source:	Buckeye Game Birds Defiance, OH	
	Defiance, OH	All birds should be from the same source.

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding study: The dietary concentrations were selected in consultation with the Sponsor, based upon results from a pilot reproduction study (Wildlife International, Ltd., Project No. 112-600; not further described) and additional toxicity information provided by the Sponsor.

b. Definitive Study

Table 2: Experimental Parameters.

Parameter	Details	Remarks Criteria
Acclimation period:	4 weeks	All birds were examined daily during acclimation, and birds
Conditions (same as test or not):	Same as test	exhibiting abnormal behavior or debilitating physical injuries were
Feeding:	Wildlife International Ltd. Game Bird Ration formulated by Cargill Animal Nutrition (Shippensburg, PA) and tap	excluded from the study. During acclimation, birds received ≤8 hours of light/day.
	water from the town of Easton were provided <i>ad libitum</i> .	Recommended observation period includes a 2-3 week health observation period prior to selection of birds for treatment. Generally,
Health (any mortality observed):	Mortality not reported.	birds should be healthy without excess mortality. Feeding should be ad libitum, and sickness, injuries or mortality should be noted.

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Danisas	D.4.2.	Remarks	
Parameter	Details	Criteria	
Test duration pre-laying exposure: egg-laying exposure: withdrawal period, if used:	11 weeks 11 weeks N/A	Recommended pre-laying exposure duration: At least 10 weeks prior to the onset of egg-laying. Recommended exposure duration with egg-laying: At least 10 weeks. Recommended withdrawal period: If reduced reproduction is evident, a withdrawal period of up to 3 weeks should be added to the test phase.	
Pen (for parental and offspring) size: construction materials:	Parents (one pair) were housed in battery cages measuring 25 x 51 x 20/26 cm high (sloping floors). Offspring (by set and group) were housed in 72 x 90 x 23 cm high battery brooders. Parental and offspring pens were	Cage size was significantly smaller than recommended. OPPTS recommends at least 5,000 cm ² per bird. In this study, the floor space was only 638 cm ² per bird. Cage sizes smaller than recommended should be shown to not adversely affect the health or reproduction of the birds.	
number:	constructed of galvanized wire mesh and galvanized sheeting. Sixteen adult pens (housing two adult birds) per level. Hatchlings	Sisal ropes were added to each adult pen for animal enrichment from the time of photostimulation to termination (Weeks 10 to 22).	
	were group-housed according to the appropriate parental concentration.	Pens Pens should have adequate room and be arranged to prevent cross-contamination. Materials Recommended materials include nontoxic material and nonbinding material, such as galvanized steel. Number At least 5 replicate pens should be used for mallards housed in groups of 7. For other arrangements, at least 12 pens should be used, but considerably more may be used if birds are kept in pairs. Chicks should be housed according to parental grouping.	

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	5.47	Remarks
Parameter	Details	Criteria
Number of birds per pen (male:female)	2 birds/pen (1 male:1 female)	
		One male and one female per pen should be used. For quail, one male and two females should be used. For ducks, two males and five females should be used.
Number of pens per group/treatment		
negative control: solvent control: treated:	N/A 16 pens 16 pens/treatment	At least 12-16 pens should be used, but considerably more if birds are kept in pairs.
Test concentrations (mg ai/kg diet) nominal:	0 (control), 160, 400, and 1000 mg ai/kg diet	Nominal concentrations were adjusted for the purity of the test substance.
measured:	<lod (control),="" 159,="" 382,="" 994="" ai="" and="" diet,="" kg="" mg="" respectively<="" td=""><td>Measured concentrations were determined at all levels during Weeks 2, 4, 5, 6, 10, 14, 18, and 22.</td></lod>	Measured concentrations were determined at all levels during Weeks 2, 4, 5, 6, 10, 14, 18, and 22.
		Recommended test concentrations include at least two concentrations other than the control; three or more will provide a better statistical analysis. The highest test concentrations should show a significant effect or be at or above the actual or expected field residue level.
Maximum labeled field residue anticipated and source of information:	Not specified	The highest test concentrations should show a significant effect or be at or above the actual or expected field residue level. The source (i.e., maximum label rate in lb ai/A and ppm), label registration no., label date, and site should be cited]

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Parameter	Details	Remarks
		Criteria
Solvent/vehicle, if used type: amount:	Corn oil 0.082% (v:w)	Reviewer-calculated: 180 mL corn oil ÷ 7938.0 g ration x 2000 g portion premix = 45.35 mL acetone, in 55,000 g final diet x 100 = 0.082% (v:w).
		Recommended solvents include corn oil or other appropriate vehicle not more than 2% of diet by weight
Was detailed description and nutrient analysis of the basal diet provided? (Yes/No)	Yes. The basal ration contained at least 27% protein and 2.5% fat, and no more than 3.8% fiber. The diet was supplemented with 5% (w:w) limestone to provide necessary calcium for proper eggshell formation.	Offspring were fed basal ration without the addition of test substance or limestone, and received a water-soluble vitamin and electrolyte mix in their water. Neither the adults nor offspring received any form of medication in their feed during the test.
		A commercial breeder feed or an equivalent that is appropriate for the test species is recommended.

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Parameter	Details	Remarks
Preparation of test diet	To prepare premixes (beginning	Criteria To improve homogeneity, the
	with the third preparation procedure on 09/28/07), corn oil	mixing procedure was changed during Week 3.
	was combined with approximately half of the needed amount of basal ration and mixed for <i>ca</i> . 5 minutes on a Hobart mixer. A portion of this mixture was blended with the appropriate quantity of test material for at least 60 seconds. The blended diet was then returned to the mixer and mixed for <i>ca</i> . 10 minutes. The remaining half of basal diet was added and the diet mixed for an additional 10 minutes. Premixes were prepared every 2 to 4 weeks, and if not used immediately after mixing, were stored frozen in plastic bags. As needed, the appropriate premix was combined with additional basal ration and limestone and mixed in a Patterson-Kelly Twin Shell Blender for approximately 20 minutes.	A premixed diet containing the test substance should be mechanically mixed with basal diet. If an evaporative vehicle is used, it should be completely evaporated prior to feeding.
Indicate whether stability and homogeneity of test material in diet determined (Yes/No)	Yes	
Were concentrations in diet verified by chemical analysis?	Yes	

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Parameter	Details	Remarks Criteria
Did chemical analysis confirm that diet was stable?	Yes, for ambient 7-day feeder storage. Frozen storage stability data were not generated (premix batches were prepared every 2 to 4 weeks and were stored frozen until needed).	Stability was assessed in treated feed prepared at all treatment levels after 7 days of ambient feeder storage during Week 3. Recoveries averaged 101, 97, and 112% of initial concentrations for the 160, 400, and 1000 mg ai/kg diet levels, respectively. Fresh diets were offered weekly (on Wednesday) during the definitive study.
and homogeneous?	Yes	Homogeneity was assessed in treated feed prepared at all treatment levels on Day 0 of Week 1. Additional samples were collected on Day 0 of Week 3 and Day 2 of Week 3 when the mixing procedure was changed to facilitate better homogeneity of the test substance in the diet. Six samples per level were collected: one sample per side from the top, middle, and bottom of the batch. Calculated coefficients of variations (CV=RSD) were 4.05, 3.34, and 3.70% for the 160, 400, and 1000 mg ai/kg diet levels, respectively (Day 2 of Week 3 data reported).
Feeding and husbandry	Feeding and husbandry conditions appeared to be adequate, given guideline recommendations.	

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Parameter	Details	Remarks	
		Criteria	
Test conditions (pre-laying) temperature: relative humidity: photoperiod:	20.6 ± 2.2°C 46 ± 16% ≤8 hr light/day up through Week 9; 17 hr light/day thereafter.	Temperature and humidity were for the adult room during the entire study. The air handling system provided up to 15 room air volumes every hour. Light intensity was approximately 405 lux (<i>ca.</i> 38 ft. candles).	
		Recommended temperature: about 21°C (70°F) Recommended relative humidity: about 55% Recommended lighting First 8 weeks: 7 h per day. Thereafter: 16-17 h per day. At least 6 foot-candles are recommended at bird level.	
Egg Collection and Incubation			
Egg collection and storage collection interval: storage temperature: storage humidity:	Daily 14.6 ± 0.1°C 70 ± 6%	Eggs should be collected daily; recommended egg storage temperature is approximately 16°C (61°F); recommended humidity is approximately 65%. Recommended collection interval: daily	
Were eggs candled for cracks prior to setting for incubation?	Yes	Eggs should be candled on day 0	
Were eggs set weekly?	Yes	Prior to setting, all eggs to be incubated were fumigated with formaldehyde gas in an airtight cabinet for <i>ca.</i> 2 hours to reduce the possibility of pathogen contamination.	
When candling was done for fertility?	Eggs were candled again on Days 11 or 12 (embryo viability) and 21 (embryo survival).	Quail: approx. day 11 Ducks: approx. day 14	
When the eggs were transferred to the hatcher?	Day 21	Bobwhite: usually day 21 Mallard: usually day 23	

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Parameter	Details	Remarks	
		Criteria	
Hatching conditions temperature:	$37.2 \pm 0.0^{\circ}$ C	Recommended temperature is 39°C	
humidity:	Ca. 77%	(102°F) Recommended humidity is 70%	
photoperiod:	16 hours light/8 hours dark (hatchlings)		
Day the hatched eggs were removed and			
counted	Days 25 or 26	Eggs for bobwhite should be removed on day 24; for mallard on day 27	
Were egg shells washed and dried for at least 48 hrs before measuring?	Yes		
Egg shell thickness no. of eggs used:	One egg was collected (when available) from each odd numbered cage during odd numbered weeks and from each even numbered cage during the even numbered weeks.	Newly hatched eggs should be collected at least once every two weeks. Thickness of the shell plus membrane should be measured to the nearest 0.01 mm with 3 - 4 measurements per shell.	
intervals:	Once weekly throughout the egg laying period.		
mode of measurement:	Five points around the equatorial circumference were measured to the nearest 0.002 mm.		
Reference chemical, if used	None used		

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2. Observations:

Table 3: Observations.

Parameter	Details	Remarks
Parameters measured		
Parental (mortality, body weight, mean feed consumption) Egg collection and subsequent development (no. of eggs laid, no. of eggs cracked, shell thickness, no. of eggs set, no. of viable embryos, no. of live 3 week embryos, no. hatched, no. of 14-day survivors, average weight of 14-d old survivors, mortality, gross pathology, others)	- mortality - body weight - food consumption - signs of toxicity - necropsy - eggs laid - eggs cracked - egg shell thickness - eggs set - viable embryos - live 3-week embryos - number of hatchlings - hatchling body weight - number of 14-day-old survivors - 14-day-old survivor body weight - signs of toxicity of hatchlings	All adult birds were subjected to gross necropsy. Recommended endpoints measured include: • Eggs laid/pen • Eggs cracked/pen • Eggs set/pen • Viable embryos/pen • Live 3-week embryos/pen • Normal hatchlings/pen • 14-day-old survivors/pen • 14-day-old survivors/pen • Weights of 14-day-old • survivors (mean per pen) • Egg shell thickness • Food consumption (mean per pen) • Initial and final body weight (mean per pen)
Indicate if the test material was regurgitated	No indications of dietary regurgitation.	
Observation intervals (for various parameters)	Parental and hatchling mortality and parental signs of toxicity were recorded once daily. Parental body weights were recorded at weeks 0 (test initiation), 2, 4, 6, 8, 10, and 22 (adult termination). Parental food consumption was measured weekly throughout the test.	Body weights and food consumption should be measured at least biweekly
Were raw data included?	Yes	

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II. RESULTS AND DISCUSSION:

A. MORTALITY:

No treatment-related mortalities occurred during the study. However, seven incidental mortalities occurred: one in the control group, two in the 160 mg ai/kg diet group, three in the 400 mg ai/kg diet group, and one in the 1000 mg ai/kg diet group.

The single control mortality was a female found dead during Week 19, without having exhibited any prior clinical signs. Necropsy indicated a neck fracture, with associated feather loss and bruising on the back of the head, and a subcutaneous hematoma and the base of the skull and upper cervical vertebra. Necropsy of the penmate was unremarkable.

The first mortality at the 160 mg ai/kg diet level was a male found dead during Week 18, without having exhibited any prior clinical signs. Necropsy indicated feather loss and bruising on the top of the skull, and a subcutaneous hematoma at the base of the skull with cranial bleeding. Necropsy of the pen-mate was unremarkable. The second mortality at this level was another male that was found dead during Week 22; foot lesions (that were subsequently bandaged) were noted during Week 17. Necropsy indicated lesions on the right foot, a friable liver, pale kidneys, and light in color and small (*ca.* 1.5 cm) testes. Necropsy of the pen-mate (the follow day at study termination) was unremarkable.

The first mortality at the 400 mg ai/kg diet level was a male that was euthanized during Week 2; loss of righting reflex was noted prior to euthanasia. Necropsy of this animal indicated lesions on the wings, loose blood in the lower trachea, a small spleen, pale kidneys, an empty crop, and bile-stained gizzard contents. Necropsy of the pen-mate was unremarkable. The second mortality at this level was a female that was found dead during Week 15; weakness and head and neck lesions were observed prior to death. Necropsy of this bird indicated extensive head and neck lesions with cranium exposure, small lacerations on the neck muscles, pale kidneys, egg yolk remnants in the abdominal cavity, and pasty cecal contents. Necropsy of the pen-mate revealed areas of hyperemia in the small intestines, but was otherwise unremarkable. The third mortality at the 400 mg ai/kg diet level was a female that was found dead during Week 19; thinness, a ruffled appearance, and lesions on both wings were observed prior to death. Necropsy indicated emaciation with a loss of muscle mass and prominent keel, little coronary fat, no abdominal fat, and lesions on the leading edge of both wings extending from shoulder to wrist with exposed tendons on the left wing and necrotic margins on both wings. In addition, pale lungs, a pale spleen, pale kidneys, and a regressed ovary were observed. Necropsy of the pen-mate revealed areas of hyperemia in the small intestines, but was otherwise unremarkable.

The single mortality at the 1000 mg ai/kg diet level was a female that was found dead during Week 19, without having exhibited any prior clinical signs. Necropsy indicated a pale spleen, and a mid-cervical vertebra fracture, with associated feather loss, bruising on the top and back of the head, and a subcutaneous hematoma at the base of the skull. Necropsy of the pen-mate indicated areas of hyperemia in the large intestines, but was otherwise unremarkable.

No other mortalities occurred during the study. Due to the timing of the mortalities, the lack of a concentration response, and the nature of lesions observed at necropsy, none of the deaths were considered to be treatment-related. The NOAEC was 1000 mg ai/kg diet.

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Treatment	Observation Period							
(mg ai/kg diet)	We	ek 7	Wee	ek 15	Week 22			
Mean-measured (and Nominal) Concentrations	No. Dead Male Female		No. Dead Male Female		No. Dead Male Female			
Control	0	0	0	0	1	0		
159 (160)	0	0	0	0	2	0		
382 (400)	1	0	1	1	1	2		
994 (1000)	0	0	0	0	0	1		

B. REPRODUCTIVE AND OTHER ENDPOINTS:

<u>Abnormal Effects/Behavior</u>: No overt signs of toxicity were observed at any treatment level. Incidental clinical observations that are normally associated with injuries (including those from pen-mate aggression) and/or pen-wear included feather loss; foot, wing, neck and head lesions; abscesses; and bruising and swelling. Lameness, ocular injury, thinness, ruffled appearance, lethargy, unilateral wing droop, and ventral head curl were also observed, but were typically associated with the incidental injuries.

One female from the 400 mg ai/kg diet level and one male from the 1000 mg ai/kg diet level were noted as thin, ruffled in appearance, congested, and coughing during Weeks 2 to 6. Furthermore, one female from the 160 mg ai/kg diet level suffered foot and hock lesions (first noted during Week 3) that healed, but restricted leg movement.

Aside from the incidental findings, all birds appeared normal throughout the study. The NOAEC for clinical signs of toxicity was 1000 mg ai/kg diet.

Food Consumption: No apparent treatment-related effects on feed consumption were evident at any treatment level, with no statistically-significant differences from the control observed at any interval for the 400 or 1000 mg ai/kg diet levels. At the 160 mg ai/kg diet level, statistically-significant (p<0.05) increases compared to the control were indicated during Weeks 6 (17 versus 15 g/bird/day for the control), and 12 (22 versus 20 g/bird/day). Since the differences were slight, not concentration-responsive, and not consistent over time, they were not considered to be related to treatment. Overall food consumption averaged 20, 21, 21, and 21 g/bird/day for the control, 160, 400, and 1000 mg ai/kg diet levels, respectively, and the corresponding estimated daily dietary doses were 0, 16.1, 40.0, and 100.9 mg ai/kg day. The NOAEC for feed consumption was 1000 mg ai/kg diet.

<u>Body Weight</u>: No apparent treatment-related effects on body weight were evident at any treatment level, with no statistically-significant differences from the control observed at any interval for any treatment level. The NOAEC for adult body weight was 1000 mg ai/kg diet.

Necropsy: There were no macroscopic findings at necropsy that were considered related to treatment.

Reproductive Effects: No treatment-related effects were evident at any treatment level, with no statistically-significant differences from the control observed for any reproductive or offspring parameter at the 160 or 1000 mg ai/kg diet levels. At the 400 mg ai/kg diet level, there was a slight statistically-significant (p<0.01) reduction in the

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number of 14-day old survivors as a percentage of hatchlings (89 versus 98% for controls). The difference observed, however, was not concentration responsive and was attributed by the study authors to low offspring survival that was observed in three pens. No other statistically-significant differences from the control were indicated at the 400 mg ai/kg diet level for any reproductive or offspring parameter. The NOAEC for all reproductive and offspring endpoints was 1000 mg ai/kg diet.

Table 5: Reproductive and Other Parameters (nominal concentrations; study author-reported)*

Parameter	Control	160 mg/kg	400 mg/kg	1000 mg/kg	NOAEC/ LOAEC
Eggs laid/pen	49	49	53	51	N/A
Eggs laid/hen/day	0.54	0.53	0.58	0.56	N/A
Eggs laid/maximum laid (%)	68	67	73	71	1000 mg/kg >1000 mg/kg
Eggs cracked	33	45	9	16	N/A
Eggs cracked/eggs laid (%)	4	7	1	2	1000 mg/kg >1000 mg/kg
Eggs set	608	596	611	680	N/A
Shell thickness (mm ± SD)	0.225 ± 0.019	0.230 ± 0.024	0.233 ± 0.011	0.225 ± 0.013	1000 mg/kg >1000 mg/kg
Viable embryos	512	516	538	626	N/A
Viable embryos/eggs set (%)	79	83	89	93	1000 mg/kg >1000 mg/kg
Live 3-week embryos	510	511	531	625	N/A
Live 3-week embryos/viable embryos (%)	100	97	99	100	1000 mg/kg >1000 mg/kg
No. of hatchlings	490	485	505	603	N/A
No. hatchlings/live 3-week embryos (%)	96	94	94	97	1000 mg/kg >1000 mg/kg
No. of hatchlings/eggs set (%)	76	76	84	90	1000 mg/kg >1000 mg/kg
Hatchling weight (g ± SD)	6 ± 0	6 ± 0	6 ± 1	6 ± 0	1000 mg/kg >1000 mg/kg
14-day old survivors	475	461	456	585	N/A
14-day old survivors weight (g ± SD)	30 ± 2	30 ± 2	28 ± 4	31 ± 2	1000 mg/kg >1000 mg/kg
14-day old	98	95	89**	97	1000 mg/kg

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Parameter	Control	160 mg/kg	400 mg/kg	1000 mg/kg	NOAEC/ LOAEC
survivors/hatchlings (%)					>1000 mg/kg
Mean food consumption (g/bird/day)	20	21	21	21	1000 mg/kg >1000 mg/kg
Weight (g) of parent females at test initiation: at onset of egg laying: at test termination:	197 202 237	202 210 245	200 206 241	198 207 236	1000 mg/kg >1000 mg/kg
Weight (g) of parent males at test initiation: at onset of egg laying: at test termination:	198 202 206	201 204 213	199 206 215	197 203 212	1000 mg/kg >1000 mg/kg
Gross pathology	No treatment-re	•	1000 mg/kg >1000 mg/kg		

^{*}The reviewer notes discrepancies in the study author's calculations.

N/A = Not statistically-analyzed.

C. REPORTED STATISTICS:

The following variables were statistically analyzed: adult body weight, adult feed consumption, eggs laid of maximum laid, eggs cracked of eggs laid, viable embryos of eggs set, live 3-week embryos of viable embryos, hatchlings of 3-week embryos, 14-day old survivors of hatchlings, hatchlings of eggs set, 14-day old survivors of eggs set, hatchlings of maximum set, 14-day old survivors of maximum set, egg shell thickness, and offspring body weight (0 and 14 days).

Each of the treatment groups was compared to the control group using an analysis of variance (ANOVA) followed by Dunnett's Multiple Comparison Procedure. Sample units were the individual pens within each experimental group, except adult body weights, where the sample unit was the individual bird. Percentage data were arcsine square root transformed prior to analysis. Nominal concentrations were used for all estimations.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Analysis was conducted using "chicks.sas" (Ver. 3; March 2002), a SAS program provided by EFED/OPP/USEPA. Data for all endpoints were examined graphically using box plots to determine if they exhibited a dose-dependent response, which was ultimately used to select the multiple comparison test to detect LOAEC and NOAEC. Data for each endpoint were tested to determine if their distributions were normal and if their variances were homogeneous using Shapiro-Wilk's and Levene's tests, respectively. Data that satisfied these assumptions were subjected to Dunnett's and William's tests and data that did not satisfy these assumptions were subjected to the non-parametric MannWhitney-U (with a Bonferroni adjustment) and Jonckheere's tests. Data for dead birds were excluded from the analyses. See Appendix I for output of reviewer's statistical verification and graphs for affected endpoints to support any reviewer-generated conclusions that may differ from those reported in the study.

^{**} Significantly different from the control at p<0.01.

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NOAEC: 944 mg ai/kg LOAEC: >944 mg ai/kg

Most Sensitive Endpoint(s): None

Table 6: Reproductive and Other Parameters (mean-measured concentrations; reviewer-reported).

Parameter	Control	159 mg ai/kg	382 mg ai/kg	994 mg ai/kg	NOAEC/ LOAEC
Eggs laid/pen	49.1	48.5	52.6	51.1	994 mg ai/kg >994 mg ai/kg
Eggs cracked/pen	2.2	3.0	0.7	1.1	994 mg ai/kg >994 mg ai/kg
Eggs not cracked/eggs laid (%)	96.1	93.0	98.8	97.9	994 mg ai/kg >994 mg ai/kg
Eggs set/pen	40.5	39.7	47.0	45.3	994 mg ai/kg >994 mg ai/kg
Shell thickness	0.22	0.23	0.23	0.23	994 mg ai/kg >994 mg ai/kg
Eggs set/eggs laid (%)	81.3	79.4	88.8	88.6	994 mg ai/kg >994 mg ai/kg
Viable embryos/pen	34.1	34.4	41.4	41.7	994 mg ai/kg >994 mg ai/kg
Viable embryos/eggs set (%)	79.1	83.0	89.2	93.0	994 mg ai/kg >994 mg ai/kg
Live embryos/pen	34.0	34.1	40.8	41.7	994 mg ai/kg >994 mg ai/kg
Live embryos/viable embryos (%)	99.7	97.2	98.6	99.8	994 mg ai/kg >994 mg ai/kg
No. of hatchlings/pen	32.7	32.3	38.8	40.2	994 mg ai/kg >994 mg ai/kg
No. of hatchlings/eggs laid (%)	63.2	63.7	74.4	79.6	994 mg ai/kg >994 mg ai/kg
No. of hatchlings/eggs set (%)	75.5	76.4	83.5	89.8	994 mg ai/kg >994 mg ai/kg
No. of hatchlings/live embryos (%)	95.7	94.2	94.3	96.6	994 mg ai/kg >994 mg ai/kg
Hatchling survival/pen	31.7	30.7	35.1	39.0	994 mg ai/kg >994 mg ai/kg

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Hatchling survival/eggs set (%)	73.6	71.8	73.5	87.3	994 mg ai/kg >994 mg ai/kg
Hatchling survival/no. of hatchlings (%)	97.5	95.0	88.7*	97.0	994 mg ai/kg >994 mg ai/kg
Hatchling weight (g)	5.9	5.9	5.8	6.2	994 mg ai/kg >994 mg ai/kg
Survivor weight (g)	29.9	30.5	28.2	31.0	994 mg ai/kg >994 mg ai/kg
Mean food consumption (g/bird/day)	20.0	20.8	20.6	20.9	994 mg ai/kg >994 mg ai/kg
Male weight gain (g)	8.7	10.6	15.2	13.5	994 mg ai/kg >994 mg ai/kg
Female weight gain (g)	40.3	43.1	41.1	39.0	994 mg ai/kg >994 mg ai/kg

^{*} Statistically different from the control at p<0.05; however, this significant effect was not considered to be an adverse effect of treatment by the reviewer or the study authors.

E. STUDY DEFICIENCIES:

There were no study deficiencies.

F. REVIEWER'S COMMENTS:

Results of the reviewer's statistical verification and conclusions were identical to the study authors'; there were no significant treatment-related effects in this study. Mean-measured concentrations are reported in the Executive Summary and Conclusions sections of the DER. Both the reviewer and the study authors detected a significant reduction (p<0.05, 9%) in the proportion of 14-day survivors of number hatched at the 382 mg ai/kg treatment level. The study authors dismissed this effect, attributing it to low survival in three pens at this level and noting that it was not a dose-dependent response; the reviewer could not confirm this claim of lower survival of a few replicate pens. However, the reviewer also dismissed the effect as treatment-related and based it on the rationale that both absolute parameters (number of hatchlings and survivors) experienced increases at the 382 mg ai/kg level (relative to the control). Furthermore, the increase in the number of hatchlings (19%, the denominator) exceeded that of the number of survivors (11%, the numerator), thereby supporting evidence for a slight, but significant reduction in the relative ratio of these endpoints, making the effect a mathematical artifact rather than a biologically-significant effect.

All validity requirements were met. Specifically, controls produced an average of 32, 14-day old survivors per hen during the 11-week production phase (minimum of 12 chicks per pen during a 10-week production phase), the egg shell thickness of control eggs was 0.225 mm (minimum of 0.19 mm for bobwhite), and control mortality was 3.1% (no more than 10% acceptable in controls).

It was reported that homogeneity was assessed in treated feed prepared at all treatment levels on Day 0 of Week 1, and that additional samples were collected on Day 0 of Week 3 and Day 2 of Week 3 when the mixing procedure was changed to facilitate better homogeneity of the test substance in the diet. However, only results from Day 2 of Week 3 were reported (in Table 4 of Appendix XIV in the study report).

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Frozen storage stability data were not provided, and premixes of treated feed were prepared at 2- to 4-week intervals and stored frozen until needed. Despite this, it was evident from the concentration verification analyses that DPX-MAT28 Technical (aminocyclopyrachlor) was stable in the treated feed, and failure to provide frozen storage stability data is not considered to have any effect on the integrity of the study.

A minor discrepancy was noted: it was reported (in Section 5.6 – Diet Sampling and Analysis) that to assess stability, samples were collected from the feeders on Day 7 of Week 1 and Day 2 of Week 4; however, in the analytical report (Table 6 of Appendix XIV), results were provided for Days 2 and 9 of Week 3.

Treated feed samples were extracted with methanol:water (80:20, v:v) by sonicating for 15 minutes, then shaking on a table-top shaker at *ca.* 250 rpm for *ca.* 60 minutes. An aliquot of the extract was centrifuged, diluted with methanol:water, and analyzed for aminocyclopyrachlor using HPLC with UV (240 nm) detection. The LOQ for the procedure was 25 mg ai/kg diet. The LOD was set at the lowest analytical standard concentration, 0.500 mg ai/L (15 ng ai on-column based upon a 30-μL injection).

Untreated feed was fortified at 50 or 1500 mg ai/kg diet and analyzed concurrently with the test samples. Recoveries ranged from 86 to 107% for all samples. Sample concentrations were not corrected for mean procedural recoveries.

The experimental dates were September 12, 2007 to March 24, 2008.

G. CONCLUSIONS:

The scientific soundness of this study is questionable, and the study is classified as invalid. Because seven incidental mortalities were observed (all of which showed external signs of injury), small cage size used in this study may have affected reproductive endpoints throughout all treatment levels, including the controls.

NOAEC: N/A LOAEC: N/A

Endpoint(s) Affected: N/A

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III. REFERENCES:

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- Merck & Co., Inc. 1991. *The Merck Veterinary Manual*. Eighth Edition. Merck & Co., Whitehouse Station, NJ. 1832 pp.
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APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

Boby	white	rep	ro,	Aminocy	clopy	yrachlo	c, MF	RID 4756012	21		<u> </u>		
	TUOTE												
Obs	TRT	EL I		ENC_EL	ES	ES_EL	VE	VE_ES	LE	LE_VE	NH	NH_EL	NH_ES
1	Ctrl	34	2	$9\overline{4}.12$	29	85.29	28	96.55	28	100.00	27	79.41	93.10
2	Ctrl	49	0	100.00	44	89.80	38	86.36	38	100.00	37	75.51	84.09
3	Ctrl	36	0	100.00	32	88.89	32	100.00	32	100.00	32	88.89	100.00
4	Ctrl	63	0	100.00	58	92.06	57	98.28	57	100.00	56	88.89	96.55
5	Ctrl	62	0	100.00	58	93.55	54	93.10	54	100.00	53	85.48	91.38
6	Ctrl	57	2	96.49	50	87.72	35	70.00	34	97.14	34	59.65	68.00
7	Ctrl	47	0	100.00	42	89.36	26	61.90	26	100.00	25	53.19	59.52
8	Ctrl	30	1	96.67	25	83.33	25	100.00	25	100.00	25	83.33	100.00
9	Ctrl	65	1	98.46	59	90.77	55	93.22	55	100.00	52	80.00	88.14
10	Ctrl	60	1	98.33	51	85.00	47	92.16	47	100.00	45	75.00	88.24
11	Ctrl	•	•	•	•	•	•	•	•	•	•	•	•
12	Ctrl	65		66.15	28	43.08	22	78.57	22	100.00	16	24.62	57.14
13	Ctrl	19		100.00	16	84.21	0	0.00	0		0	0.00	0.00
14	Ctrl	57	0	100.00	52	91.23	52	100.00	51	98.08	49	85.96	94.23
15	Ctrl	29	1	96.55	8	27.59	4	50.00	4	100.00	4	13.79	50.00
16	Ctrl	64	3	95.31	56	87.50	37	66.07	37	100.00	35	54.69	62.50
17	Dose1		1	98.53	61	89.71	57	93.44	56	98.25	54	79.41	88.52
18	Dose1		0	100.00	64	92.75	57	89.06	56	98.25	54	78.26	84.38
19	Dose1		4	93.94	57	86.36	46	80.70	46	100.00	44	66.67	77.19
20	Dose1		0	100.00	15	83.33	15	100.00	15	100.00	15	83.33	100.00
21	Dose1		1	98.11	48	90.57	47	97.92	47	100.00	45	84.91	93.75
22	Dose1			69.05	15	35.71	14	93.33	14	100.00	8	19.05	53.33
23	Dose1		2	96.15	46	88.46	45	97.83	45	100.00	45	86.54	97.83
24	Dosel			89.47	45	78.95	39	86.67	38	97.44	36	63.16	80.00
25	Dose1		1	98.36 100.00	54	88.52 84.21	48	88.89	48	100.00	46	75.41	85.19 100.00
26 27	Dose1			100.00	16 57	91.94	16 44	100.00 77.19	16	100.00	16 37	84.21 59.68	64.91
28	Dose:		0	100.00	43	89.58	35	81.40	44 35	100.00	34	70.83	79.07
29	Dose			52.94	7	20.59	3	42.86	2	66.67	2	5.88	28.57
30	Dose:		0	100.00	20	83.33	4	20.00	4	100.00	4	16.67	20.00
31	Dose:			100.00				20.00					20.00
32	Dose1		1	98.18	48	87.27	46	95.83	45	97.83	45	81.82	93.75
33	Dose		0	100.00	65	92.86	59	90.77	59	100.00	59	84.29	90.77
34	Dose		0	100.00	45	90.00	45	100.00	45	100.00	43	86.00	95.56
35	Dose		0	100.00	31	91.18	30	96.77	29	96.67	29	85.29	93.55
36	Dose		0	100.00	46	90.20	45	97.83	44	97.78	42	82.35	91.30
37	Dose		0	100.00	9	81.82	9	100.00	9	100.00	9	81.82	100.00
38	Dose2		0	100.00	53	91.38	53	100.00	53	100.00	53	91.38	100.00
39	Dose		2	96.67	53	88.33	25	47.17	25	100.00	23	38.33	43.40
40	Dose		2	96.83	55	87.30	43	78.18	43	100.00	42	66.67	76.36
41	Dose2		0	100.00	56	90.32	53	94.64	53	100.00	52	83.87	92.86
42	Dose2	54	1	98.15	48	88.89	45	93.75	45	100.00	45	83.33	93.75
43	Dose							•				•	
44	Dose2	2 .											
45	Dose2	2 63	1	98.41	57		51	89.47	49	96.08	47	74.60	82.46
46	Dose2	2 48	0	100.00	41	85.42	34	82.93	32	94.12	17	35.42	41.46
47	Dose2	2 60	3	95.00	52	86.67	46	88.46	45	97.83	44	73.33	84.62
48	Dose2	2 .											
49	Dose3	3 3 6	0	100.00	32	88.89	32	100.00	32	100.00	31	86.11	96.88
50	Dose3	3 72	2	97.22	64	88.89	46	71.88	46	100.00	40	55.56	62.50
51	Dose				0		0	•	0		0	•	•
52	Dose			100.00	52	89.66	47	90.38	46	97.87	46	79.31	88.46
53	Dose			100.00	39		39	100.00		100.00	38	90.48	97.44
54	Dose3			100.00	47		46			100.00	44		93.62
55	Dose			100.00	44				42		40	83.33	90.91
56	Dose			89.74	30		30	100.00			30	76.92	100.00
57	Dose3	3 64	1	98.44	58	90.63	53	91.38	53	100.00	53	82.81	91.38

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58	Dose3		95	.38 56	86.15	50	89.29	50	100.0	0 50	76.92	89.29
59	Dose3								100.0			
60 61	Dose3 Dose3				91.80 89.06		.00.00 85.96		100.0			
62	Dose3					53	98 15		100.0			85.19
63			. 98			37	98.15 82.22 .00.00		100.0			77.78
64	Dose3			.00 46		46 1	.00.00		100.0			100.00
Boby	white :	repro,		ocyclopy:			4756012	21				
				(continu								
	TRT	NH_LE					TWTAH					WTGAINF
1 2	Ctrl Ctrl		3 27 37 34		100.00 91.89				28 28	20 19	12 17	42 35
3	Ctrl					0.2	24 6		33	20	-2	40
4			5 53			0.2	24 6 25 6		32	21	20	40
5			.5 53	91.38		0.2	21 6		30	22	12	57
6		100.0							28	18	11	41
7		96.1		57.14					27	20	3	36
8 9	Ctrl Ctrl	94.5					(1 6		30 31	19 20	0 1	26 50
10	Ctrl	95.7) 3 6		32		9	49
11	Ctrl						.5 .			•	•	•
12	Ctrl	72.7		57.14			.9 6		26		12	42
13	Ctrl			0.00					•	18	-2	15
14	Ctrl	96.0		92.31			23 6		29	22	16	47
15 16	Ctrl Ctrl				100.00 94.29		20 6		30 34	18 25	1 21	35 50
17	Dose1						26 6		29	21	14	49
18	Dose1						2 6		30	22	4	50
19	Dose1			75.44			22 6		33	21	16	43
20	Dose1				100.00		2.3 7		34	19	15	45
21	Dose1		4 44	91.67			23 6		30	19	8	56
22	Dose1		4 8	53.33			20 6		32	19 21 21 22	11	38
23 24	Dose1 Dose1		41 36				.3 b		30 32	21 21	0 5	53 32
25	Dose1								33	22	•	
26		100.0		68.75			2.5 5		30	21 22 22	4	28
27	Dose1						2.5 6		31	21	9	53
28	Dose1						23 6 .9 5		29	20	20	24
29				28.57			.9 5		24	21	2	28
30 31	Dose1 Dose1		10 4	20.00	100.00	0.2			30	22	8	33
32	Dose1			87.50	93.33	0.2			31	21	32	• 66
33	Dose2			84.62	93.22	0.2	22 6 25 6		28	22	14	
34	Dose2			93.33			25 6		30	18	3	46
35	Dose2			67.74			25 5		25	17	6	
				78.26			21 6		29	20		
37 38	Dose2 Dose2				66.67 96.23				21 28	20 22	24 29	22 55
39	Dose2				100.00				30	21	20	46
40	Dose2				73.81				24	20	3	56
41	Dose2	98.1	.1 48	85.71	92.31	0.2	22 7		35	22	18	75
42	Dose2		0 42	87.50		0.2	2.4 6		32	22	18	32
43	Dose2		•	•	•	•			•	•	•	•
44 45	Dose2 Dose2			71 03	87.23		. 4 5		26	23	23	44
46	Dose2			39.02	94.12	0.2	23 7		26	21	13	47
47	Dose2		8 44		100.00	0.2	25 6		32		9	24
48	Dose2			•								•
49	Dose3				100.00				33	22	7	53
50 51	Dose3 Dose3		0 35		87.50	0.2	2.4 7		31	22 19	5 -2	47 -13
~ ±		•	9	•	•	•	•		-		_	

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52	Dose3 100.00	46	88.46	100.00	0.21	6	29	21	5	48	
53	Dose3 97.44	37	94.87	97.37	0.23	6	28	23	1	-19	
54	Dose3 95.65	42	89.36	95.45	0.23	6	30	19	12	46	
55	Dose3 95.24	40	90.91	100.00	0.23	6	30	18	23	52	
56	Dose3 100.00	29	96.67	96.67	0.23	6	32	19	12	11	
57	Dose3 100.00	52	89.66	98.11	0.22	6	31	24	14	48	
58	Dose3 100.00	50	89.29	100.00	0.21	6	31	22	22	49	
59	Dose3 .										
60	Dose3 98.21	52	92.86	94.55	0.22	6	33	20	24	50	
61	Dose3 100.00	48	84.21	97.96	0.25	7	29	21	11	68	
62	Dose3 86.79	44	81.48	95.65	0.20	7	33	22	28	55	
63	Dose3 94.59	34	75.56	97.14	0.23	6	34	21	30	55	
64	Dose3 100.00	45	97.83	97.83	0.22	6	30	20	10	35	

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE EL (Eggs Laid)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion P-value Test Stat P-value Test Stat

0.902 <.001 0.316 0.814 USE NON-PARAMETRIC TESTS

BASIC SU	JMMAR	Y STATIS	TICS				
Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.I	Interval
Ctrl	15	49.13	15.61	4.03	31.76	40.49,	57.78
Dose1	15	48.53	17.41	4.50	35.88	38.89,	58.18
Dose2	13	52.62	15.42	4.28	29.32	43.29,	61.94
Dose3	15	51.13	17.69	4.57	34.60	41.34,	60.93
Level		Median	Min	Max	%of Control(means)	%Reduct	cion(means)
Ctrl		57.00	19.00	65.00	•	•	or (modific)
Dose1		53.00	18.00	69.00	98.78	1.2	22
Dose2		58.00	11.00	70.00	107.09	-7.0)9
Dose3		52.00	0.00	72.00	104.07	-4.0	7

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom TestStat P-value 0.49

MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon	adjust)p-value	Jonckheere p-value
Ctrl	57.00			•
Dose1	53.00		1.000	0.467
Dose2	58.00		1.000	0.668
Dose3	52.00		0.787	0.727

SUMMARY NOEC LOEC

MannWhit (Bonf adjust) Dose3 >highest dose Jonckheere Dose3 >highest dose

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE NEG EC (Eggs Cracked)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.599	<.001	2.701	0.055	USE NON-PARAMETRIC TESTS

BASIC SU	JMMAR	Y STATIST	'ICS				
Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Inter	rval
Ctrl	15	2.20	5.56	1.43	252.61	0.00, 5.	28
Dose1	15	3.00	5.00	1.29	166.67	0.23, 5.	77
Dose2	13	0.69	1.03	0.29	149.00	0.07, 1.	32
Dose3	15	1.07	1.49	0.38	139.35	0.24, 1.	89
Level		Median	Min	Max	%of Control (means) %Reduction(means)
Ctrl		1.00	0.00	22.00	•	•	
Dose1		1.00	0.00	16.00	136.36	-36.36	
Dose2		0.00	0.00	3.00	31.47	68.53	
Dose3		0.00	0.00	4.00	48.48	51.52	

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests

Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom TestStat P-value

1.76 0.623

MannWhit(Bon) - testing each trt median signif. greater than control Jonckheere - test assumes dose-response relationship, testing positive trend

Level	Median	MannWhit(Bon adjust)p-v	alue Jonckheere p-value
Ctrl	1.00	•	•
Dose1	1.00	1.000	0.292
Dose2	0.00	1.000	0.741
Dose3	0.00	1.000	0.725
SUMMARY	· (D 6 1)		OEC

MannWhit (Bonf adjust) Dose3 >highest dose
Jonckheere Dose3 >highest dose

PMRA Submission Number {.....}

SUMMARY

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE ENC EL ((EL-EC)/EL (%)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.595 <.001 4.037 0.012 USE NON-PARAMETRIC TESTS ******************** BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 15 96.14 8.53 2.20 8.87 91.41, 100.00 Dosel 15 92.98 13.65 3.52 14.68 85.42, 100.00 Dose2 13 98.85 1.71 0.47 1.73 97.82, 99.88 Dose3 14 97.93 3.05 0.82 3.12 96.17, 99.70
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 98.46
 66.15
 100.00
 .
 .

 98.36
 52.94
 100.00
 96.72
 3.28

 100.00
 95.00
 100.00
 102.82
 -2.82

 99.22
 89.74
 100.00
 101.87
 -1.87
 Median Level Ctrl Dose1 Dose2 ****************** NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 1.94 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend Median MannWhit (Bon adjust) p-value Jonckheere p-value Ctrl 98.46 98.36 1.000 0.325 Dose1 1.000 Dose2 100.00 0.810 0.765 Dose3 99.22 1.000

JMMARYNOECLOECMannWhit (Bonf adjust)Dose3>highest doseJonckheereDose3>highest dose

PMRA Submission Number {.....}

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121

EPA MRID Number 47560121

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	15	40.53	16.47	4.25	40.64	31.41, 49.66
Dose1	15	39.73	19.46	5.03	48.98	28.96, 50.51
Dose2	13	47.00	14.17	3.93	30.14	38.44, 55.56
Dose3	15	45.33	15.82	4.09	34.90	36.57, 54.10
Level		Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl		44.00	8.00	59.00	•	•
Dose1		46.00	7.00	64.00	98.03	1.97
Dose2		52.00	9.00	65.00	115.95	-15.95
Dose3		47.00	0.00	64.00	111.84	-11.84

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value $3 \hspace{1.5cm} \text{1.18} \hspace{1.5cm} \text{0.758}$

 $\begin{tabular}{ll} MannWhit(Bon) - testing each trt median signif. less than control \\ Jonckheere - test assumes dose-response relationship, testing negative trend \\ \end{tabular}$

Level	Median	MannWhit(Bon	adjust)p-val	ue Jonckheere p-value
Ctrl	44.00		•	•
Dose1	46.00		1.000	0.450
Dose2	52.00		1.000	0.769
Dose3	47.00		1.000	0.802
SUMMARY		NOEC	LOE	IC .

MannWhit (Bonf adjust) Dose3 >highest dose
Jonckheere Dose3 >highest dose

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE ES EL (EggsSet/EggsLaid (%)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.613 < .001 4.240 0.009 USE NON-PARAMETRIC TESTS ******************* BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 15 81.29 19.12 4.94 23.52 70.70, 91.88 Dosel 15 79.42 21.33 5.51 26.85 67.61, 91.23 Dose2 13 88.83 2.95 0.82 3.32 87.05, 90.62 Dose3 14 88.58 4.15 1.11 4.68 86.19, 90.98 Min Max %of Control(means) %Reduction(means)
27.59 93.55
20.59 92.75 97.70 2.30
81.82 92.86 109.28 -9.28
76.92 92.86 108.97 -8.97 Median Level 87.72 Ctrl Dose1 87.27 90.00 81.82 Dose2 89.83 76.92 ****************** NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 3.89 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend Median MannWhit (Bon adjust) p-value Jonckheere p-value Ctrl 87.72 0.828 0.267 Dose1 87.27

Dose2 Dose3	90.00 89.83			1.000			0.817 0.936
SUMMARY MannWhit Jonckhee	•	adjust)	NOEC Dose3 Dose3		LOEC >highest >highest		

PMRA Submission Number {.....}

SUMMARY

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE VE (Viable Embryo(d14)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.929 0.002 1.526 0.218 USE NON-PARAMETRIC TESTS ******************** BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 15 34.13 17.47 4.51 51.19 24.46, 43.81 Dosel 15 34.40 18.71 4.83 54.39 24.04, 44.76 Dose2 13 41.38 13.65 3.79 32.99 33.13, 49.64 Dose3 15 41.73 13.80 3.56 33.06 34.09, 49.37
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 35.00
 0.00
 57.00
 .
 .

 44.00
 3.00
 57.00
 100.78
 -0.78

 45.00
 9.00
 59.00
 121.24
 -21.24

 46.00
 0.00
 56.00
 122.27
 -22.27
 Level Ctrl Dose1 Dose2 ****************** NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 2.07 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend Median MannWhit (Bon adjust) p-value Jonckheere p-value Ctrl 35.00 44.00 1.000 0.566 Dose1 1.000 Dose2 45.00 0.820 Dose3 46.00 1.000 0.919

PMRA Submission Number {......}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE VE ES (ViableEmbryo/EggsSet (%)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.784 <.001 2.662 0.057 USE NON-PARAMETRIC TESTS ******************* BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 15 79.08 27.06 6.99 34.22 64.09, 94.07 Dosel 15 83.01 22.53 5.82 27.14 70.53, 95.49 Dose2 13 89.23 14.32 3.97 16.05 80.57, 97.89 Dose3 14 93.04 8.49 2.27 9.12 88.14, 97.94
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 92.16
 0.00
 100.00
 .
 .

 89.06
 20.00
 100.00
 104.97
 -4.97

 93.75
 47.17
 100.00
 112.83
 -12.83

 96.66
 71.88
 100.00
 117.65
 -17.65
 Level Ctrl Dose1 Dose2 ******************** NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 3.35 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend Median MannWhit(Bon adjust)p-value Jonckheere p-value

Ctrl 92.16	•	•
Dose1 89.06	1.000	0.607
Dose2 93.75	1.000	0.835
Dose3 96.66	1.000	0.966
SUMMARY MannWhit (Bonf adjust) Jonckheere		EC highest dose highest dose
0011011110020	20000	

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE LE (Live Embryo (d21)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.930 0.002 1.473 0.232 USE NON-PARAMETRIC TESTS ******************** BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 15 34.00 17.40 4.49 51.17 24.36, 43.64 Dosel 15 34.07 18.60 4.80 54.61 23.76, 44.37 Dose2 13 40.85 13.67 3.79 33.46 32.59, 49.11 Dose3 15 41.67 13.77 3.56 33.05 34.04, 49.29
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 34.00
 0.00
 57.00
 .
 .

 44.00
 2.00
 56.00
 100.20
 -0.20

 45.00
 9.00
 59.00
 120.14
 -20.14

 46.00
 0.00
 56.00
 122.55
 -22.55
 Level Ctrl Dose1 Dose2 ****************** NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 2.13 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend Median MannWhit (Bon adjust) p-value Jonckheere p-value Ctrl 34.00 44.00 1.000 0.550 Dose1 1.000 Dose2 45.00 0.805 Dose3 46.00 1.000 0.925 UMMARY NOEC LOEC
MannWhit (Bonf adjust) Dose3 >highest dose
Jonckheere Dose3 >highest dose SUMMARY

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE LE VE (LiveEmbryo/ViableEmbryo (%)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.378 <.001 2.877 0.045 USE NON-PARAMETRIC TESTS ******************** BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 14 99.66 0.89 0.24 0.89 99.15, 100.00 Dosel 15 97.23 8.51 2.20 8.75 92.52, 100.00 Dose2 13 98.65 1.98 0.55 2.01 97.45, 99.85 Dose3 14 99.85 0.57 0.15 0.57 99.52, 100.00
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 100.00
 97.14
 100.00
 .
 .

 100.00
 66.67
 100.00
 97.56
 2.44

 100.00
 94.12
 100.00
 98.99
 1.01

 100.00
 97.87
 100.00
 100.19
 -0.19
 Level Ctrl Dose1 Dose2 ****************** NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 5.74 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend Median MannWhit (Bon adjust) p-value Jonckheere p-value Ctrl 100.00 100.00 1.000 0.135 Dose1 1.000 Dose2 100.00 0.059 1.000 0.594 Dose3 100.00 UMMARY NOEC LOEC
MannWhit (Bonf adjust) Dose3 >highest dose
Jonckheere Dose3 >highest dose SUMMARY

PMRA Submission Number {.....}

Dose2

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121

EPA MRID Number 47560121

ANALYSIS RESULTS FOR VARIABLE NH (Number Hatched) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.934 0.004 1.328 0.275 USE NON-PARAMETRIC TESTS ******************* BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 15 32.67 17.10 4.41 52.34 23.20, 42.14 Dosel 15 32.33 18.25 4.71 56.45 22.23, 42.44 Dose2 13 38.85 14.90 4.13 38.35 29.84, 47.85 Dose3 15 40.20 13.39 3.46 33.30 32.79, 47.61
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 34.00
 0.00
 56.00
 .
 .

 37.00
 2.00
 54.00
 98.98
 1.02

 43.00
 9.00
 59.00
 118.92
 -18.92

 44.00
 0.00
 55.00
 123.06
 -23.06
 Level Ctrl Dose1

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 2.36

MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	Manni	Whit(Bon	adjust)p	-value	Joncki	neere p-value
Ctrl	34.00						•
Dose1	37.00			1.000			0.550
Dose2	43.00			1.000			0.811
Dose3	44.00			1.000			0.926
SUMMARY MannWhi Jonckhe	it (Bonf eere	adjust)	NOEC Dose3 Dose3		LOEC >highest >highest		

EPA MRID Number 47560121 PMRA Submission Number {.....}

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE NH EL (NumberHatched/EggsLaid (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.841	<.001	4.096	0.011	USE NON-PARAMETRIC TESTS

BASIC SU	JMMAR	Y STATIS	TICS				
Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Int	cerval
Ctrl	15	63.23	28.89	7.46	45.69	47.23,	79.23
Dose1	15	63.72	27.16	7.01	42.62	48.68,	78.76
Dose2	13	74.36	17.82	4.94	23.96	63.60,	35.13
Dose3	14	79.55	9.63	2.57	12.11	73.99,	35.11
Level		Median	Min	Max	%of Control (means)) %Reduction	on(means)
Ctrl		75.51	0.00	88.89	•		
Dose1		75.41	5.88	86.54	100.78	-0.78	
Dose2		82.35	35.42	91.38	117.61	-17.61	
Dose3		81.06	55.56	90.48	125.82	-25.82	

 ${\tt NON-PARAMETRIC~ANALYSES} \qquad {\tt - use~alpha-level=0.05~for~all~tests}$ Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 3.83

MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhi	t(Bon a	adjust)p-	-value	Jonckh	neere p-value
Ctrl	75.51						
Dose1	75.41			1.000			0.426
Dose2	82.35			1.000			0.828
Dose3	81.06			1.000			0.960
SUMMARY		N	IOEC		LOEC		
MannWh	it (Bonf	adjust)	Dose3		>highest	dose	
Jonckh	eere		Dose3		>highest	dose	

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE NH ES (NumberHatched/EggsSet (%)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.853 <.001 2.854 0.046 USE NON-PARAMETRIC TESTS ******************** BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 15 75.53 26.89 6.94 35.60 60.64, 90.42 Dosel 15 76.43 24.81 6.41 32.46 62.69, 90.17 Dose2 13 83.54 19.42 5.39 23.25 71.81, 95.28 Dose3 14 89.83 10.13 2.71 11.27 83.98, 95.68
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 88.14
 0.00
 100.00
 .
 .

 84.38
 20.00
 100.00
 101.20
 -1.20

 91.30
 41.46
 100.00
 110.62
 -10.62

 91.14
 62.50
 100.00
 118.94
 -18.94
 Level Ctrl Dose1 Dose2 ******************* NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 2.99 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend Median MannWhit(Bon adjust)p-value Jonckheere p-value

	110011	110111111111111111111111111111111111111	aa, acc, p		 .coro p .ara	
Ctrl	88.14					
Dose1	84.38		1.000		0.508	
Dose2	91.30		1.000		0.752	
Dose3	91.14		1.000		0.945	
SUMMARY MannWh Jonckh	it (Bonf a eere	NOEC adjust) Dose3 Dose3		LOEC >highest >highest		

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE NH LE (NumberHatched/LiveEmbryo (%)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.560 <.001 0.734 0.537 USE NON-PARAMETRIC TESTS ******************* BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 14 95.72 6.91 1.85 7.22 91.73, 99.71 Dosel 15 94.21 11.03 2.85 11.71 88.11, 100.00 Dose2 13 94.28 12.61 3.50 13.37 86.66, 100.00 Dose3 14 96.55 4.55 1.21 4.71 93.93, 99.18 88.11, 100. 86.66, 100.00 93.93, 99.18
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 96.90
 72.73
 100.00
 .
 .

 96.43
 57.14
 100.00
 98.43
 1.57

 97.78
 53.13
 100.00
 98.50
 1.50

 97.83
 86.79
 100.00
 100.87
 -0.87
 Median Level 96.90 Ctrl Dose1 Dose2 ****************** NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 0.14 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend Median MannWhit (Bon adjust) p-value Jonckheere p-value Ctrl 96.90 96.43 1.000 0.527 Dose1 97.78 1.000 Dose2 0.584 97.83 Dose3 1.000 0.635 UMMARY NOEC LOEC
MannWhit (Bonf adjust) Dose3 >highest dose
Jonckheere Dose3 >highest dose SUMMARY

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE HS (Hatching Survival(d14)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.942 0.008 1.245 0.303 USE NON-PARAMETRIC TESTS ******************* BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 15 31.67 16.38 4.23 51.73 22.59, 40.74 Dosel 15 30.73 17.73 4.58 57.70 20.91, 40.55 Dose2 13 35.08 14.72 4.08 41.96 26.18, 43.97 Dose3 15 39.00 13.07 3.37 33.50 31.76, 46.24 46.24
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 33.00
 0.00
 53.00
 .
 .

 37.00
 2.00
 53.00
 97.05
 2.95

 41.00
 6.00
 55.00
 110.77
 -10.77

 42.00
 0.00
 52.00
 123.16
 -23.16
 Level Ctrl Dose1 Dose2 ******************* NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 2.16 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bor	n adjust)p	-value .	Jonckh	eere p-value
Ctrl	33.00		•			•
Dose1	37.00		1.000			0.525
Dose2	41.00		1.000			0.704
Dose3	42.00		1.000			0.918
SUMMARY		NOEC		LOEC		
MannWh	it (Bonf a	djust) Dose3	3	>highest	dose	
Jonckh	eere	Dose	3	>highest	dose	

PMRA Submission Number {......} EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE HS_ES (HatchingSurvival/EggsSet (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 $\,$

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

JMMAR	Y STATIS	rics				
N	Mean	StdDev	StdErr	Coef of Var	95% Conf.I	nterval
15	73.60	26.37	6.81	35.83	59.00,	88.21
15	71.81	22.61	5.84	31.48	59.29,	84.33
13	73.49	18.25	5.06	24.83	62.46,	84.52
14	87.34	11.27	3.01	12.91	80.83,	93.84
	Median	Min	Max	%of Control(means)	%Reduct	ion(means)
	83.05	0.00	100.00	•		
	79.69	20.00	100.00	97.56	2.4	4
	78.26	39.02	96.23	99.85	0.1	5
	89.51	54.69	97.83	118.66	-18.6	6
	JMMAR' N 15 15 13 14	N Mean 15 73.60 15 71.81 13 73.49 14 87.34 Median 83.05 79.69 78.26	15 73.60 26.37 15 71.81 22.61 13 73.49 18.25 14 87.34 11.27 Median Min 83.05 0.00 79.69 20.00 78.26 39.02	N Mean StdDev StdErr 15 73.60 26.37 6.81 15 71.81 22.61 5.84 13 73.49 18.25 5.06 14 87.34 11.27 3.01 Median Min Max 83.05 0.00 100.00 79.69 20.00 100.00 78.26 39.02 96.23	N Mean StdDev StdErr Coef of Var 15 73.60 26.37 6.81 35.83 15 71.81 22.61 5.84 31.48 13 73.49 18.25 5.06 24.83 14 87.34 11.27 3.01 12.91 Median Min Max %of Control (means) 83.05 0.00 100.00 . 79.69 20.00 100.00 97.56 78.26 39.02 96.23 99.85	N Mean StdDev StdErr Coef of Var 95% Conf.I 15 73.60 26.37 6.81 35.83 59.00, 15 71.81 22.61 5.84 31.48 59.29, 13 73.49 18.25 5.06 24.83 62.46, 14 87.34 11.27 3.01 12.91 80.83, Median Min Max %of Control (means) %Reduct 83.05 0.00 100.00 79.69 20.00 100.00 97.56 2.4 78.26 39.02 96.23 99.85 0.1

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests

Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom TestStat P-value

6.74 0.081

MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon	adjust)p-value	Jonckheere p-value
Ctrl	83.05			•
Dose1	79.69		0.933	0.302
Dose2	78.26		1.000	0.320
Dose3	89.51		1.000	0.946

SUMMARY NOEC LOEC

MannWhit (Bonf adjust) Dose3 >highest dose
Jonckheere Dose3 >highest dose

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE HS NH (HatchingSurvival/NumberHatched (%)) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.829 < .001 6.242 0.001 USE NON-PARAMETRIC TESTS ******************** BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 14 97.47 2.92 0.78 2.99 95.78, 99.15 Dosel 15 95.01 8.14 2.10 8.57 90.50, 99.52 Dose2 13 88.67 11.03 3.06 12.44 82.00, 95.34 Dose3 14 97.02 3.28 0.88 3.38 95.12, 98.91 Median Level 98.98 Ctrl Dose1 97.78 Dose2 93.22 97.60 87.50 100.00 99.54 0.46 ****************** NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 9.15 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend Median MannWhit (Bon adjust) p-value Jonckheere p-value Ctrl 98.98 0.813 Dose1 97.78 0.261 04

Dose2 Dose3	93.22 97.60		0.0 1.0		0.004 0.166
SUMMARY MannWhit Jonckhee	•	adjust)	NOEC Dose1 Dose3	LOEC Dose2 >highest d	ose

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE THICK (Eggshell thickness)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion

Test Stat P-value Test Stat P-value 0.992 0.963 2.442 0.074 USE PARAMETRIC TESTS

BASIC SU	JMMAR	Y STATIST	'ICS				
Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.I	nterval
Ctrl	15	0.22	0.02	0.00	8.62	0.21,	0.24
Dose1	15	0.23	0.02	0.01	10.20	0.22,	0.24
Dose2	13	0.23	0.01	0.00	4.55	0.23,	0.24
Dose3	14	0.23	0.01	0.00	5.80	0.22,	0.23
Level		Median	Min	Max	%of Control(means)	%Reduct	ion(means)
Ctrl		0.23	0.19	0.26	•		
Dose1		0.23	0.19	0.27	102.58	-2.5	8
Dose2		0.23	0.21	0.25	104.01	-4.0	1
Dose3		0.23	0.20	0.25	100.40	-0.4	0

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Analysis of Variance (ANOVA) - overall F-test

Numerator df Denominator df F-stat P-value
3 53 0.80 0.501

Level	Mean	Dunnett	Isotonic	Williams			Tukey p-	values	
		p-value	mean	p-value	Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	0.22		0.23	•	0.805	0.540	0.999		
Dose1	0.23	0.957	0.23	0.846	•	0.964	0.877	•	•
Dose2	0.23	0.987	0.23	0.867	•		0.635	•	•
Dose3	0.23	0.801	0.23	0.694	•	•	•		•

SUMMARY	NOEC	LOEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE HATWT (Hatchling Weight) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Conclusion Test Stat P-value Test Stat P-value 0.837 <.001 3.335 0.026 USE NON-PARAMETRIC TESTS ******************* BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 14 5.93 0.27 0.07 4.51 5.77, 6.08 Dosel 15 5.93 0.46 0.12 7.71 5.68, 6.19 Dose2 13 5.85 0.69 0.19 11.78 5.43, 6.26 Dose3 14 6.21 0.43 0.11 6.85 5.97, 6.46
 Level
 Median
 Min
 Max
 %of Control(means)
 %Reduction(means)

 Ctrl
 6.00
 5.00
 6.00
 .
 .
 .

 Dosel
 6.00
 5.00
 7.00
 100.08
 -0.08

 Dose2
 6.00
 5.00
 7.00
 98.61
 1.39

 Dose3
 6.00
 6.00
 7.00
 104.82
 -4.82
 Level ******************** NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 4.56 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon a	adjust)p-value	Jonckheere p-value
Ctrl	6.00		•	•
Dose1	6.00	- -	1.000	0.500
Dose2	6.00	_	1.000	0.299
Dose3	6.00	-	1.000	0.896
SUMMARY		NOEC	LOEC	
MannWh	it (Bonf ad	just) Dose3	>highest	dose
Jonakhe	eere	Dose3	>highest	dose

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE SURVWT (Survivor Wt (d14))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion
Test Stat P-value Test Stat P-value

0.982 0.543 2.340 0.084 USE PARAMETRIC TESTS

BASIC SU	JMMARY	STATIST	rics				
Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.I	nterval
Ctrl	14	29.86	2.35	0.63	7.87	28.50,	31.21
Dose1	15	30.53	2.36	0.61	7.72	29.23,	31.84
Dose2	13	28.15	3.78	1.05	13.44	25.87,	30.44
Dose3	14	31.00	1.80	0.48	5.80	29.96,	32.04
					^ C ~ . 1/	0-1	
Level	1	Median	Min	Max	%of Control(means)	%Reduct	ion(means)
Ctrl		30.00	26.00	34.00	•	•	
Dose1		30.00	24.00	34.00	102.26	-2.2	:6
Dose2		28.00	21.00	35.00	94.30	5.7	0
Dose3		31.00	28.00	34.00	103.83	-3.8	13

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Analysis of Variance (ANOVA) - overall F-test

Numerator df Denominator df F-stat P-value 3 52 2.99 0.039

Level	Mean	Dunnett	Isotonic	Williams			Tukey p-v	zalues	
		p-value	mean	p-value	Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	29.86		30.21	•	0.901	0.348	0.664		
Dose1	30.53	0.928	30.21	0.726		0.094	0.964	•	
Dose2	28.15	0.118	29.63	0.518			0.035	•	
Dose3	31.00	0.976	29.63	0.533	•	•	•	•	•

SUMMARY	NOEC	LOEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE FOOD (Food Consumption)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value

0.973 0.220 1.007 0.397 USE PARAMETRIC TESTS

BASIC SU	UMMARY	STATIST	ICS				
Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interv	al
Ctrl	15	20.00	1.89	0.49	9.45	18.95, 21.0	5
Dose1	15	20.80	1.08	0.28	5.20	20.20, 21.4	0
Dose2	13	20.62	1.71	0.47	8.29	19.58, 21.6	5
Dose3	15	20.87	1.68	0.43	8.07	19.93, 21.8	0
Level]	Median	Min	Max	%of Control (means)	%Reduction(m	eans)
Ctrl		20.00	18.00	25.00	•		
Dose1		21.00	19.00	22.00	104.00	-4.00	
Dose2		21.00	17.00	23.00	103.08	-3.08	
Dose3		21.00	18.00	24.00	104.33	-4.33	

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Analysis of Variance (ANOVA) - overall F-test

Numerator df Denominator df F-stat P-value
3 54 0.89 0.450

Level	Mean	Dunnett	Isotonic	Williams	Tukey p-values				
		p-value	mean	p-value	Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	20.00		20.57		0.533	0.748	0.464		
Dose1	20.80	0.987	20.57	0.898		0.990	0.999	•	
Dose2	20.62	0.966	20.57	0.914			0.976		
Dose3	20.87	0.991	20.57	0.931	•	•	•	•	٠

SUMMARY	NOEC	LOEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE WTGAINM (Male wt gain)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion

Test Stat P-value Test Stat P-value 0.976 0.322 0.357 0.784 USE PARAMETRIC TESTS

BASIC SU	JMMARY	STATIS	TICS				
Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval	
Ctrl	15	8.73	8.00	2.06	91.55	4.31, 13.16	
Dose1	14	10.57	8.45	2.26	79.90	5.69, 15.45	
Dose2	13	15.15	8.15	2.26	53.80	10.23, 20.08	
Dose3	15	13.47	9.86	2.55	73.24	8.01, 18.93	
Level		Median	Min	Max	%of Control (means)	%Reduction(means)
Ctrl		11.00	-2.00	21.00	•	•	
Dose1		8.50	0.00	32.00	121.05	-21.05	
Dose2		17.00	3.00	29.00	173.52	-73.52	
Dose3		12.00	-2.00	30.00	154.20	-54.20	

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Analysis of Variance (ANOVA) - overall F-test

Numerator df Denominator df F-stat P-value
3 53 1.55 0.212

Level	Mean	Dunnett	Isotonic	Williams	Tukey p-values				
		p-value	mean	p-value	Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	8.73		11.89		0.940	0.218	0.447		
Dose1	10.57	0.911	11.89	0.901		0.522	0.805	•	
Dose2	15.15	0.998	11.89	0.920		•	0.955	•	
Dose3	13.47	0.992	11.89	0.936					•

SUMMARY	NOEC	LOEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

PMRA Submission Number {.....}

EPA MRID Number 47560121

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121 ANALYSIS RESULTS FOR VARIABLE WTGAINF (Female wt gain) TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01 Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05 Use parametric analyses if neither test rejected, otherwise non-parametric analyses. Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion Test Stat P-value Test Stat P-value 0.907 <.001 3.281 0.028 USE NON-PARAMETRIC TESTS ******************* BASIC SUMMARY STATISTICS Level N Mean StdDev StdErr Coef of Var 95% Conf.Interval Ctrl 15 40.33 10.40 2.68 25.78 34.58, 46.09 Dosel 15 43.07 12.16 3.14 28.23 36.33, 49.80 Dose2 13 41.08 20.71 5.74 50.42 28.56, 53.59 Dose3 15 39.00 25.47 6.58 65.31 24.90, 53.10
 Median
 Min
 Max
 % of Control (means)
 % Reduction (means)

 41.00
 15.00
 57.00
 .
 .

 45.00
 24.00
 66.00
 106.78
 -6.78

 46.00
 -5.00
 75.00
 101.84
 -1.84

 48.00
 -19.00
 68.00
 96.69
 3.31
 Level Ctrl Dose1 Dose2 ******************* NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests Kruskal-Wallis test - equality among treatment groups Degrees of Freedom TestStat P-value 1.12 0.773 MannWhit(Bon) - testing each trt median signif. less than control Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bo	n adjust)p	-value .	Jonckh	eere p-value
Ctrl	41.00		•			•
Dose1	45.00		1.000			0.719
Dose2	46.00		1.000			0.648
Dose3	48.00		1.000			0.813
SUMMARY		NOEC		LOEC		
MannWhit	: (Bonf	adjust) Dose	3	>highest	dose	
Jonckhee	ere	Dose	3	>highest	dose	

Box Plot:

Bobwhite repro, Aminocyclopyrachlor, MRID 47560121

